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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,483	09/19/2001	Robert L. Arslanian	300622007800	3156

25226 7590 09/09/2003
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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/957,483

Applicant(s)

ARSLANIAN ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Application Status

1. Claims 1-47 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-10, 12-33, and 35-39, drawn to recombinant host cells of the suborder *Cystobacterineae* containing an expression vector encoding a function polyketide synthase, classified in class 435, subclass 252.3.
 - II. Claim 11, drawn to methods of making a polyketide, classified in class 435, subclass 76.
 - III. Claim 34, drawn to epothilone derivative compounds, classified in class 568, subclass 382.
 - IV. Claims 40-41, drawn to methods for purifying an epothilone from a host cell, classified in class 435, subclass 76.
 - V. Claim 42, drawn to crystalline epothilone D, classified in class 568, subclass 382.
 - VI. Claims 43-46, drawn to methods for fermentation of a *Myxococcus* host cell comprising culturing using a fatty acid or oil as a carbon source, classified in class 435, subclass 252.1.
 - VII. Claim 47, drawn to compounds of the genus in Claim 47, classified in class 568, subclass 382.

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3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the host cells can be used in a materially different process of using that product, such as in the recombinant production of the polyketide synthase enzymes which can then be used to raise antibodies *in vivo*. Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to Groups III, V, and VII by virtue of the fact that the host cells can be used to make the polyketide products in Groups III, V, and VII. However, the products of Group I are wholly distinct as host cells while the compounds of Groups III, V, and VII are small organic molecules without wholly distinct structure and function from that of the products of Group I. Moreover, the products of Groups III, V, and VII can be produced without use of the host cells of Group I. Thus, Group I is patentably distinct from Groups III, V, and VII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to the methods of Group IV as a product that can be used in the methods. However, the methods of Group IV utilize any polyketide-producing cell and are not

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limited to methods of using the product of Group I. Moreover, the products of Group I can be used in wholly different methods such as in the recombinant production of polyketide synthase enzymes. Thus, the particulars of Group I are not required for the practice of the methods of Group IV. Therefore, Group I is patentably distinct from Group IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to the methods of Group VI as a product that can be used in the methods. However, the methods of Group VI utilize any *Myxococcus* host cell and are not limited to methods of using the product of Group I. Moreover, the products of Group I can be used in wholly different methods such as in the recombinant production of polyketide synthase enzymes. Thus, the particulars of Group I are not required for the practice of the methods of Group VI. Therefore, Group I is patentably distinct from Group VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group II is related to Groups III, V, and VII as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the polyketide products can be made by a materially different process, such as full organic synthesis. Thus, Group II is patentably distinct from Groups III, V, and VII. Because these inventions are distinct for the reasons given above and have acquired a separate status in

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the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group II is related to Groups IV and VI as methods related to polyketides and/or *Myxococcus* host cells. However, the methods are wholly distinct by virtue of their distinct method steps. Moreover, Group II is a generic method of producing polyketides using particular host cells, Group IV is a specific method for purifying particular polyketides (epothilones) and Group VI is a specific fermentation method for *Myxococcus* using a particular additive. These Groups have wholly different directions as to their method steps and products. Thus, Groups II, IV, and VI are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups III, V, and VII are related to Group IV as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the polyketides of Groups III, V, and VII can be purified (made) in wholly distinct fashion using organic synthetic methods in the absence of host cells, wherein the purification steps are wholly distinct from those in Group IV. Thus, Groups III, V, and VII are patentably distinct from Group IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Groups III, V, and VII are related to each other by virtue of the general similarities in chemical structures since all are polyketide compounds. However, these general similarities do not render the compounds unique in the art, thus, the compounds must be searched individually using their particular structures that render them distinct not only from the art but also from compounds in the other Groups. Thus, Groups III, V, and VII are patentably distinct. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Groups V and/or VII, restriction for examination purposes as indicated is proper.

Restriction of Species

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

In Group I, the species are *Angiococcus*, *Myxococcus stipitatus*, *M. fulvus*, *M. xanthus*, *M. virescens*, *Corallococcus*, *Cystobacter*, *Melittangium*, *Stigmatella*, and *Archangium*.

The species are patentably distinct because they wholly distinct products with different physical characteristics related to their taxonomic classification.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-3, 12-14, 16-18, 21-28, 30-33, and 35-39 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Election

5. A telephone call was made to Ted Apple on September 8, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

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Conclusion

6. A complete reply to the instant Office action must include an election of invention to be examined. If Applicants elect Group I, an election of species is also required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

September 8, 2003

